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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,815	03/16/2001	Andreas Burgard	00/067 NUT	6739

7590

06/06/2002

ProPat LLC
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Charlotte, NC 28211

EXAMINER


WALLS, DIONNE A

ART UNIT	PAPER NUMBER
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1731

DATE MAILED: 06/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/810,815	Applicant(s) BURGARD ET AL. 	
	Examiner Dionne A. Walls	Art Unit 1731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4 and 10, drawn to compound/solid or liquid preparation, classified in class 131, subclass 274.
 - II. Claims 5-7, drawn to a process for producing a compound, classified in class 546, subclass 279.4.
 - III. Claim 8, drawn to a method of manufacturing a chewing gum, classified in class 546, subclass 279.4.
 - IV. Claim 9, drawn to a method of manufacturing a chewing tablet, classified in class 546, subclass 279.4.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I,II; I,III; and I,IV are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, for Inventions I and II, the product can be made by another and materially different process, such as one wherein nicotine and the other additives are merely dry-mixed together – without the presence of a solvent. For Inventions I,III and I,IV, the process as claimed can be used to make another and materially different product such as a liquid medicament.

3. Inventions II,III; II,IV and III,IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II has separate utility such as a process for the production of a generic compound; invention III has separate utility such as a process for the production of a chewing tablet; and invention IV has separate utility such as a process for the production of a chewing gum. See MPEP § 806.05(d).

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, and the search required for Group III is not required for Group II, etc, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Dr. Klaus Schweitzer on May 23rd, 2002 a provisional election was made with traverse to prosecute the invention of I, claims 1-4 and 10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding the recitation of claim 1, in lines 3 and 4 of this claim, Applicant has recited "physiologically acceptable salts a physiologically acceptable acid", however this does not make sense, grammatically. Therefore, the Examiner has interpreted this phrase as "physiologically acceptable salts or a physiologically acceptable acid" – which is consistent with the language in the specification. Also, the examiner believes that claim 1 should be written to more clearly recite if Applicant intends to claim a compound of nicotine/sweetener; or a compound of nicotine/sweeteners/acid-addition salt/physiologically acceptable salts; or a compound or nicotine/sweeteners/acid-addition salt/physiologically acceptable acid. The Examiner has interpreted the claims in this manner; however, the claim language as currently recited makes it unclear what "compound" or "compounds" Applicant specifically intends to claim. Clarification is requested.

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3. Regarding claim 3, the word "aspartame-like" renders the claim unclear because the addition of the word "-like" to an otherwise definite expression extends the scope of the expression so as to render it indefinite. See MPEP § 2173.05(b,d).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-4 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 196 39 343.

DE 196 39 343 discloses all that is recited in the claims, since it discloses a compressed formulation which contains nicotine and acesulfame K (See attached abstract of English translation).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over DE 196 39 343 in view of Applicant's Admitted Art and WO 00/12067.

While DE 196 39 343 may not explicitly state that the nicotine and sweetener are present in a molar ratio of 1:1 or 1:2, Applicant has admitted that it is known that nicotine has an unpleasant taste (see page 2, line 32). Further, WO 00/12067 discloses, in its "Background of Invention" section that oral drugs, with an organic base, possess a very bitter taste which, for acceptable oral administration, requires masking by familiar methods, such as the incorporation of sweeteners in large amounts to render the medicinal bases palatable. The novel compound of WO 00/12067 comprises a sweetener which has been added to a bitter-tasting drug in a 1:1 molar ratio. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a sweetener to the nicotine in a molar amount that equals the molar amount of nicotine in order to effectively mask the bitter taste of the nicotine so that the formulation has a more pleasing taste to the consumer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne A. Walls whose telephone number is (703) 305-0933. The examiner can normally be reached on Mon-Fri, 7AM - 4:30PM (Every other Friday off).

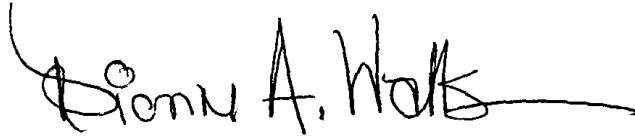
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven P. Griffin can be reached on (703) 308-1164. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

A handwritten signature in black ink, appearing to read "Dionne A. Walls", followed by a long horizontal flourish.

Dionne A. Walls
June 2, 2002